

AMENDED IN ASSEMBLY SEPTEMBER 3, 2003

AMENDED IN ASSEMBLY JULY 16, 2003

AMENDED IN SENATE APRIL 24, 2003

AMENDED IN SENATE MARCH 27, 2003

**SENATE BILL**

**No. 490**

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**Introduced by Senator Alpert**  
**(Coauthor: Senator Bowen)**  
(Coauthor: Assembly Member Cohn)

February 20, 2003

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An act to amend Section 4052 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 490, as amended, Alpert. Pharmacy: prescriptions.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy and makes it responsible for regulating the practice of pharmacy. A knowing violation of the Pharmacy Law is a crime. Under that law, a pharmacist may not, in general, furnish a dangerous drug except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian. However, existing law authorizes a pharmacist to initiate emergency contraception drug therapy in accordance with standardized protocols developed by the pharmacist and an authorized prescriber acting within his or her scope of practice.

This bill would also authorize a pharmacist to furnish emergency contraception drug therapy in accordance with a standardized procedure or protocol developed and approved by both the board and the Medical Board of California, in consultation with specified entities.

The bill would require a pharmacist to complete a specified training program before performing emergency contraception drug therapy. Because a violation of this bill would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

*This bill would also incorporate additional changes to Section 4052 of the Business and Professions Code proposed by SB 545 that would become operative only if SB 545 and this bill are both enacted and become effective on or before January 1, 2004, and this bill is enacted last.*

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. Section 4052 of the Business and Professions
- 2 Code is amended to read:
- 3 4052. (a) Notwithstanding any other provision of law, a
- 4 pharmacist may:
- 5 (1) Furnish a reasonable quantity of compounded medication
- 6 to a prescriber for office use by the prescriber.
- 7 (2) Transmit a valid prescription to another pharmacist.
- 8 (3) Administer, orally or topically, drugs and biologicals
- 9 pursuant to a prescriber's order.
- 10 (4) Perform the following procedures or functions in a licensed
- 11 health care facility in accordance with policies, procedures, or
- 12 protocols developed by health professionals, including physicians,
- 13 pharmacists, and registered nurses, with the concurrence of the
- 14 facility administrator:
- 15 (A) Ordering or performing routine drug therapy related
- 16 patient assessment procedures including temperature, pulse, and
- 17 respiration.
- 18 (B) Ordering drug therapy related laboratory tests.
- 19 (C) Administering drugs and biologicals by injection pursuant
- 20 to a prescriber's order (the administration of immunizations under



1 the supervision of a prescriber may also be performed outside of  
2 a licensed health care facility).

3 (D) Initiating or adjusting the drug regimen of a patient  
4 pursuant to an order or authorization made by the patient's  
5 prescriber and in accordance with the policies, procedures, or  
6 protocols of the licensed health care facility.

7 (5) (A) Perform the following procedures or functions as part  
8 of the care provided by a health care facility, a licensed home  
9 health agency, a licensed clinic in which there is a physician  
10 oversight, a provider who contracts with a licensed health care  
11 service plan with regard to the care or services provided to the  
12 enrollees of that health care service plan, or a physician, in  
13 accordance, as applicable, with policies, procedures, or protocols  
14 of that facility, the home health agency, the licensed clinic, the  
15 health care service plan, or that physician, in accordance with  
16 subparagraph (C):

17 (i) Ordering or performing routine drug therapy related patient  
18 assessment procedures including temperature, pulse, and  
19 respiration.

20 (ii) Ordering drug therapy related laboratory tests.

21 (iii) Administering drugs and biologicals by injection pursuant  
22 to a prescriber's order (the administration of immunizations under  
23 the supervision of a prescriber may also be performed outside of  
24 a licensed health care facility).

25 (iv) Initiating or adjusting the drug regimen of a patient  
26 pursuant to a specific written order or authorization made by the  
27 patient's prescriber for the individual patient, and in accordance  
28 with the policies, procedures, or protocols of the health care  
29 facility, home health agency, licensed clinic, health care service  
30 plan, or physician. Adjusting the drug regimen does not include  
31 substituting or selecting a different drug, except as authorized by  
32 the protocol. The pharmacist shall provide written notification to  
33 the patient's prescriber, or enter the appropriate information in an  
34 electronic patient record system shared by the prescriber, of any  
35 drug regimen initiated pursuant to this clause within 24 hours.

36 (B) A patient's prescriber may prohibit, by written instruction,  
37 any adjustment or change in the patient's drug regimen by the  
38 pharmacist.

39 (C) The policies, procedures, or protocols referred to in this  
40 paragraph shall be developed by health care professionals,



1 including physicians, pharmacists, and registered nurses, and, at  
2 a minimum, meet all of the following requirements:

3 (i) Require that the pharmacist function as part of a  
4 multidisciplinary group that includes physicians and direct care  
5 registered nurses. The multidisciplinary group shall determine the  
6 appropriate participation of the pharmacist and the direct care  
7 registered nurse.

8 (ii) Require that the medical records of the patient be available  
9 to both the patient's prescriber and the pharmacist.

10 (iii) Require that the procedures to be performed by the  
11 pharmacist relate to a condition for which the patient has first been  
12 seen by a physician.

13 (iv) Except for procedures or functions provided by a health  
14 care facility, a licensed clinic in which there is physician oversight,  
15 or a provider who contracts with a licensed health care plan with  
16 regard to the care or services provided to the enrollees of that  
17 health care service plan, require the procedures to be performed in  
18 accordance with a written, patient-specific protocol approved by  
19 the treating or supervising physician. Any change, adjustment, or  
20 modification of an approved preexisting treatment or drug therapy  
21 shall be provided in writing to the treating or supervising physician  
22 within 24 hours.

23 (6) Manufacture, measure, fit to the patient, or sell and repair  
24 dangerous devices or furnish instructions to the patient or the  
25 patient's representative concerning the use of those devices.

26 (7) Provide consultation to patients and professional  
27 information, including clinical or pharmacological information,  
28 advice, or consultation to other health care professionals.

29 (8) (A) Furnish emergency contraception drug therapy in  
30 accordance with either of the following:

31 ~~(A)~~

32 (i) Standardized procedures or protocols developed by the  
33 pharmacist and an authorized prescriber who is acting within his  
34 or her scope of practice.

35 ~~(B)~~

36 (ii) Standardized procedures or protocols developed and  
37 approved by both the board and the Medical Board of California  
38 in consultation with the American College of Obstetricians and  
39 Gynecologists, the California Pharmacist Association, and other  
40 appropriate entities. Both the board and the Medical Board of

1 California shall have authority to ensure compliance with this  
2 ~~subparagraph~~ clause, and both boards are specifically charged  
3 with the enforcement of this provision with respect to their  
4 respective licensees. Nothing in this ~~subparagraph~~ clause shall be  
5 construed to expand the authority of a pharmacist to prescribe any  
6 prescription medication.

7 ~~(9)~~

8 (B) Prior to performing a procedure authorized under  
9 ~~paragraph (8)~~ this paragraph, a pharmacist shall complete a  
10 training program on emergency contraception consisting of at  
11 least one hour of approved continuing education on emergency  
12 contraception drug therapy.

13 (b) (1) Prior to performing any procedure authorized by  
14 paragraph (4) of subdivision (a), a pharmacist shall have received  
15 appropriate training as prescribed in the policies and procedures  
16 of the licensed health care facility.

17 (2) Prior to performing any procedure authorized by paragraph  
18 (5) of subdivision (a), a pharmacist shall have either (A)  
19 successfully completed clinical residency training or (B)  
20 demonstrated clinical experience in direct patient care delivery.

21 (3) For each emergency contraception drug therapy initiated  
22 pursuant to paragraph (8) of subdivision (a), the pharmacist shall  
23 provide the recipient of the emergency contraception drugs with  
24 a standardized factsheet that includes, but is not limited to, the  
25 indications for use of the drug, the appropriate method for using  
26 the drug, the need for medical followup, and other appropriate  
27 information. The board shall develop this form in consultation  
28 with the State Department of Health Services, the American  
29 College of Obstetricians and Gynecologists, the California  
30 Pharmacists Association, and other health care organizations. The  
31 provisions of this section do not preclude the use of existing  
32 publications developed by nationally recognized medical  
33 organizations.

34 (c) Nothing in this section shall affect the requirements of  
35 existing law relating to maintaining the confidentiality of medical  
36 records.

37 (d) Nothing in this section shall affect the requirements of  
38 existing law relating to the licensing of a health care facility.

39 ~~SEC. 2.~~

1     *SEC. 1.5. Section 4052 of the Business and Professions Code*  
2     *is amended to read:*

3     4052. (a) Notwithstanding any other provision of law, a  
4     pharmacist may:

5         (1) Furnish a reasonable quantity of compounded medication  
6         to a prescriber for office use by the prescriber.

7         (2) Transmit a valid prescription to another pharmacist.

8         (3) Administer, orally or topically, drugs and biologicals  
9         pursuant to a prescriber's order.

10        (4) Perform the following procedures or functions in a licensed  
11        health care facility in accordance with policies, procedures, or  
12        protocols developed by health professionals, including physicians,  
13        pharmacists, and registered nurses, with the concurrence of the  
14        facility administrator:

15           (A) Ordering or performing routine drug therapy-related  
16           patient assessment procedures including temperature, pulse, and  
17           respiration.

18           (B) Ordering drug therapy-related laboratory tests.

19           (C) Administering drugs and biologicals by injection pursuant  
20           to a prescriber's order (the administration of immunizations under  
21           the supervision of a prescriber may also be performed outside of  
22           a licensed health care facility).

23           (D) Initiating or adjusting the drug regimen of a patient  
24           pursuant to an order or authorization made by the patient's  
25           prescriber and in accordance with the policies, procedures, or  
26           protocols of the licensed health care facility.

27        (5) (A) Perform the following procedures or functions as part  
28        of the care provided by a health care facility, a licensed home  
29        health agency, a licensed clinic in which there is a physician  
30        oversight, a provider who contracts with a licensed health care  
31        service plan with regard to the care or services provided to the  
32        enrollees of that health care service plan, or a physician, in  
33        accordance, as applicable, with policies, procedures, or protocols  
34        of that facility, the home health agency, the licensed clinic, the  
35        health care service plan, or that physician, in accordance with  
36        subparagraph (C):

37           (i) Ordering or performing routine drug therapy-related patient  
38           assessment procedures including temperature, pulse, and  
39           respiration.

40           (ii) Ordering drug therapy-related laboratory tests.

1 (iii) Administering drugs and biologicals by injection pursuant  
2 to a prescriber's order (the administration of immunizations under  
3 the supervision of a prescriber may also be performed outside of  
4 a licensed health care facility).

5 (iv) Initiating or adjusting the drug regimen of a patient  
6 pursuant to a specific written order or authorization made by the  
7 patient's prescriber for the individual patient, and in accordance  
8 with the policies, procedures, or protocols of the health care  
9 facility, home health agency, licensed clinic, health care service  
10 plan, or physician. Adjusting the drug regimen does not include  
11 substituting or selecting a different drug, except as authorized by  
12 the protocol. The pharmacist shall provide written notification to  
13 the patient's prescriber, or enter the appropriate information in an  
14 electronic patient record system shared by the prescriber, of any  
15 drug regimen initiated pursuant to this clause within 24 hours.

16 (B) A patient's prescriber may prohibit, by written instruction,  
17 any adjustment or change in the patient's drug regimen by the  
18 pharmacist.

19 (C) The policies, procedures, or protocols referred to in this  
20 paragraph shall be developed by health care professionals,  
21 including physicians, pharmacists, and registered nurses, and, at  
22 a minimum, meet all of the following requirements:

23 (i) Require that the pharmacist function as part of a  
24 multidisciplinary group that includes physicians and direct care  
25 registered nurses. The multidisciplinary group shall determine the  
26 appropriate participation of the pharmacist and the direct care  
27 registered nurse.

28 (ii) Require that the medical records of the patient be available  
29 to both the patient's prescriber and the pharmacist.

30 (iii) Require that the procedures to be performed by the  
31 pharmacist relate to a condition for which the patient has first been  
32 seen by a physician.

33 (iv) Except for procedures or functions provided by a health  
34 care facility, a licensed clinic in which there is physician oversight,  
35 or a provider who contracts with a licensed health care plan with  
36 regard to the care or services provided to the enrollees of that  
37 health care service plan, require the procedures to be performed in  
38 accordance with a written, patient-specific protocol approved by  
39 the treating or supervising physician. Any change, adjustment, or  
40 modification of an approved preexisting treatment or drug therapy



1 shall be provided in writing to the treating or supervising physician  
2 within 24 hours.

3 (6) Manufacture, measure, fit to the patient, or sell and repair  
4 dangerous devices or furnish instructions to the patient or the  
5 patient's representative concerning the use of those devices.

6 (7) Provide consultation to patients and professional  
7 information, including clinical or pharmacological information,  
8 advice, or consultation to other health care professionals.

9 (8) ~~Initiate~~—(A) *Furnish* emergency contraception drug  
10 therapy in accordance with ~~standardized~~ *either of the following*:

11 (i) *Standardized* procedures or protocols developed by the  
12 pharmacist and an authorized prescriber who is acting within his  
13 or her scope of practice. ~~Prior~~

14 (ii) *Standardized procedures or protocols developed and*  
15 *approved by both the board and the Medical Board of California*  
16 *in consultation with the American College of Obstetricians and*  
17 *Gynecologists, the California Pharmacist Association, and other*  
18 *appropriate entities. Both the board and the Medical Board of*  
19 *California shall have authority to ensure compliance with this*  
20 *clause, and both boards are specifically charged with the*  
21 *enforcement of this provision with respect to their respective*  
22 *licensees. Nothing in this clause shall be construed to expand the*  
23 *authority of a pharmacist to prescribe any prescription*  
24 *medication.*

25 (B) ~~Prior to performing any a procedure authorized under this~~  
26 ~~paragraph, a pharmacist shall have completed~~ *complete* a training  
27 ~~program on emergency contraception, which includes, but is not~~  
28 ~~limited to, conduct of sensitive communications, quality~~  
29 ~~assurance, referral to additional services, and documentation that~~  
30 ~~consists of at least one hour of approved continuing education on~~  
31 ~~emergency contraception drug therapy.~~

32 (C) *A pharmacist, pharmacist's employer, or pharmacist's*  
33 *agent may not directly charge a patient a separate consultation fee*  
34 *for emergency contraception drug therapy services initiated*  
35 *pursuant to this paragraph, but may charge an administrative fee*  
36 *not to exceed ten dollars (\$10) above the retail cost of the drug.*  
37 *Upon an oral, telephonic, electronic, or written request from a*  
38 *patient or customer, a pharmacist or pharmacist's employee shall*  
39 *disclose the total retail price that a consumer would pay for*  
40 *emergency contraception drug therapy. As used in this*



1 *subparagraph, total retail price includes providing the consumer*  
2 *with specific information regarding the price of the emergency*  
3 *contraception drugs and the price of the administrative fee*  
4 *charged. This limitation is not intended to interfere with other*  
5 *contractually agreed upon terms between a pharmacist, a*  
6 *pharmacist's employer, or a pharmacist's agent, and a health care*  
7 *service plan or insurer. Patients who are insured or covered and*  
8 *receive a pharmacy benefit that covers the cost of emergency*  
9 *contraception shall not be required to pay an administrative fee.*  
10 *These patients shall be required to pay copayments pursuant to the*  
11 *terms and conditions of their coverage. The provisions of this*  
12 *subparagraph shall cease to be operative for dedicated emergency*  
13 *contraception drugs when these drugs are reclassified as*  
14 *over-the-counter products by the federal Food and Drug*  
15 *Administration.*

16 *(D) A pharmacist may not require a patient to provide*  
17 *individually identifiable medical information that is not specified*  
18 *in Section 1707.1 of Title 16 of the California Code of Regulations*  
19 *before initiating emergency contraception drug therapy pursuant*  
20 *to this paragraph.*

21 *(b) (1) Prior to performing any procedure authorized by*  
22 *paragraph (4) of subdivision (a), a pharmacist shall have received*  
23 *appropriate training as prescribed in the policies and procedures*  
24 *of the licensed health care facility.*

25 *(2) Prior to performing any procedure authorized by paragraph*  
26 *(5) of subdivision (a), a pharmacist shall have either (A)*  
27 *successfully completed clinical residency training or (B)*  
28 *demonstrated clinical experience in direct patient care delivery.*

29 *(3) For each emergency contraception drug therapy initiated*  
30 *pursuant to paragraph (8) of subdivision (a), the pharmacist shall*  
31 *provide the recipient of the emergency contraception drugs with*  
32 *a standardized factsheet that includes, but is not limited to, the*  
33 *indications for use of the drug, the appropriate method for using*  
34 *the drug, the need for medical followup, and other appropriate*  
35 *information. The board shall develop this form in consultation*  
36 *with the State Department of Health Services, the American*  
37 *College of Obstetricians and Gynecologists, the California*  
38 *Pharmacists Association, and other health care organizations. The*  
39 *provisions of this section do not preclude the use of existing*

1 publications developed by nationally recognized medical  
2 organizations.

3 (c) Nothing in this section shall affect the requirements of  
4 existing law relating to maintaining the confidentiality of medical  
5 records.

6 (d) Nothing in this section shall affect the requirements of  
7 existing law relating to the licensing of a health care facility.

8 *SEC. 2. Section 1.5 of this bill incorporates amendments to*  
9 *Section 4052 of the Business and Professions Code proposed by*  
10 *both this bill and SB 545. It shall only become operative if (1) both*  
11 *bills are enacted and become effective on or before January 1,*  
12 *2004, (2) each bill amends Section 4052 of the Business and*  
13 *Profession Code, and (3) this bill is enacted after SB 545, in which*  
14 *case Section 1 of this bill shall not become operative.*

15 *SEC. 3. No reimbursement is required by this act pursuant to*  
16 *Section 6 of Article XIII B of the California Constitution because*  
17 *the only costs that may be incurred by a local agency or school*  
18 *district will be incurred because this act creates a new crime or*  
19 *infraction, eliminates a crime or infraction, or changes the penalty*  
20 *for a crime or infraction, within the meaning of Section 17556 of*  
21 *the Government Code, or changes the definition of a crime within*  
22 *the meaning of Section 6 of Article XIII B of the California*  
23 *Constitution.*

